

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

_____	)	
UNITED STATES	)	<b>REDACTED</b>
	)	<b>(Filed Publicly)</b>
v.	)	
	)	
WILLIAM FACTEAU	)	Criminal No. 15-10076-ADB
	)	
Defendant	)	
_____	)	

**SENTENCING MEMORANDUM OF WILLIAM FACTEAU**

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## **INTRODUCTION**

On July 20, 2016, after a 30-day trial, the jury rejected the heart of the government's criminal charges in this case and acquitted William Facteau<sup>1</sup> on every count that accused him of fraud, falsity, deception, or misrepresentation. Specifically, the jury found Mr. Facteau not guilty of conspiracy, not guilty of wire fraud, not guilty of causing the introduction of adulterated or misbranded devices into interstate commerce with the intent to defraud or mislead, and not guilty of misleading labeling.

The sole counts of conviction involved strict liability misdemeanor violations of the Food, Drug and Cosmetic Act, stemming from Acclarent's alleged introduction of its Stratus sinus spacer into interstate commerce for an intended use the FDA had not cleared. These misdemeanors – unlike the felony counts on which the jury acquitted Mr. Facteau – required no finding by the jury that Mr. Facteau knowingly engaged in any wrongdoing. Mr. Facteau's good faith belief that he was following the law as he understood it was no defense. Rather, the jury was instructed that to convict on the Indictment's misdemeanor charges, it need only find that Mr. Facteau held a position of responsibility within Acclarent that provided him with sufficient authority to prevent or correct the charged adulteration and misbranding violations, and that violations nonetheless occurred and were not corrected.

The jury's determination that Mr. Facteau was not guilty of committing any of the fraudulent or deceptive acts with which the government charged him obviously is of great relevance to Mr. Facteau's sentencing. Most fundamentally, it undercuts the government's continuing effort to portray Mr. Facteau as the ringleader of a purported scheme to deceive and mislead the FDA into issuing a 510(k) clearance for the Stratus. The jury rejected that

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<sup>1</sup> This memorandum focuses on Mr. Facteau. Mr. Fabian, whom the jury also acquitted of the same charges, has submitted his own sentencing brief.

allegation, and the government cannot simply disregard that verdict and seek to have Mr. Facteau sentenced as if he had committed the conduct for which the jury acquitted him.

Contrary to the government's depiction, Mr. Facteau is a person whose entire life has been characterized by hard work, honesty, deeply held principles, and empathy and caring for others. Approximately four dozen letters attesting to these attributes have been submitted to the Court in connection with Mr. Facteau's sentencing. Writer after writer has described Mr. Facteau as highly ethical, a devoted and compassionate friend and father, and a gifted leader who has dedicated his nearly 30-year career to catalyzing the launch of innovative medical devices with "breakthrough technology" that have revolutionized the care and improved the lives of hundreds of thousands of patients. Mr. Facteau is praised as someone who "genuinely cares about people, especially patients in need," "an exemplary professional," "highly ethical," "one of the best CEOs in the business," and "the most honest, genuine, and sincere boss I've ever known."

Those close to Mr. Facteau have observed the "enormous toll" the government's prosecution has had on him and his family. Extending back to April 9, 2015, the date on which the government arrested Mr. Facteau at his home despite his offers to self-surrender, Mr. Facteau has paid a substantial price and suffered significant consequences – to his reputation, his family, and his personal freedom. For more than half a decade, he has lived under the cloud of the government's charges, the supervision of the Probation Department, and the strain and uncertainty of this ongoing criminal case.

No further punishment is necessary or warranted to accomplish the purposes of sentencing. In recognition of the release conditions under which he has lived for nearly six years, Mr. Facteau respectfully requests that he receive a sentence of "time served" on the

misdemeanor violations found by the jury and be allowed to move forward with his life. Such an outcome would permit him to continue his efforts to make amends to his family for the impact this case has had on them, and also to pour renewed energy into the young medical device company he joined after leaving Acclarent, whose 200 employees are dependent on Mr. Facteau’s vision and leadership as they work on a revolutionary hearing aid that won the Gold 2020 Edison Award for Innovation and that *Time* Magazine recently included on its list of the “Best Inventions of 2020.”<sup>2</sup>

### **PROCEDURAL AND FACTUAL BACKGROUND**

#### **I. Mr. Facteau’s Personal Background**

Mr. Facteau is 51 years old. Presentence Investigation Report (“PSR”) ¶ 99. Born in Lake Placid, he moved to Florida with his father at age nine when his parents divorced, where he lived until attending college in Connecticut. *Id.*

Mr. Facteau moved to California in 2000 and continues to reside there. He has five children and two stepchildren, whose ages range from 8 (daughter) to 24 (stepson). PSR ¶¶ 107-117. Mr. Facteau shares physical and legal custody of his three youngest children (ages 8, 9, and 12) with their mother, from whom Mr. Facteau was divorced in 2016 – the year this case went to trial. PSR ¶ 110. His other children are over age 18.

Since 2013, Mr. Facteau has been employed as the chief executive officer of Earlens, a medical device company based in Menlo Park that employs approximately 200 people. PSR ¶ 126. Prior to that position, from 2004 to 2012, Mr. Facteau served as chief executive officer of Acclarent, whose Stratus device has been the focus of this case.

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<sup>2</sup> See <https://edisonawards.com/winners2020.php> and <https://time.com/collection/best-inventions-2020/5911312/earlens-contact-hearing-solution/>

## II. The Government's Theory of Prosecution

The government returned a sealed indictment of Mr. Facteau and co-defendant Patrick Fabian to this Court on April 8, 2015. Despite substantial pre-indictment communications, which included an offer by defense counsel to turn in Mr. Facteau's passport and coordinate his immediate self-surrender, the government arrested Mr. Facteau at his home in the early morning hours of April 9, 2015. Without objection from the prosecutors who handled his initial appearance in the Northern District of California, Mr. Facteau was released on conditions. He promptly traveled to Boston, as his counsel had said he would, and was arraigned in this District on April 14, 2015.

Both in the indictment and in statements made since the outset of the case, the government repeatedly has claimed that this case is “about fraud: false and misleading speech, fraudulent conduct, false submissions to the FDA, wire fraud and securities fraud.” *E.g.*, Gov't's Opp'n to Defs.' Mot. to Dismiss at 10 (Dkt. #224). That theory of prosecution constituted the heart of the government's case and was the basis on which the government opposed Mr. Facteau's motions to dismiss, justified its position on disputed evidentiary issues, grounded its proposed jury instructions, and framed its presentation to the jury at trial.<sup>3</sup> Indeed, the government asserted during pre-trial proceedings that the fraudulent conspiracy charged in the indictment was so widespread that it encompassed more than 80 unindicted co-conspirators, a number that equated to more than 25% of Acclarent's entire workforce. This assertion – as implausible as it was – rendered it effectively impossible for the defendants to persuade any former Acclarent employees to testify for the defense at trial, given their concern that doing so

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<sup>3</sup> See also 2/4/16 Mot. Hr'g Tr. 86:16-19 (“[T]he allegation at the core of this case, is that what they did with this device was false and misleading . . . .”); *id.* at 114:18-24 (“[F]raud . . . [T]hat's really what this case is about and it's fraud, it's false and misleading labeling . . . .”).

might cause them to be moved from the “unindicted” to the “indicted” side of the government’s vast ledger.

### **III. The Evidence at Trial**

Despite a trial that lasted six weeks, the government failed to prove any of its assertions of fraud, much less a criminal conspiracy at Acclarent involving 80+ participants. Instead, the evidence – which was introduced almost entirely through witnesses called by the government – established the following:

1. Acclarent was an innovative company whose products helped to revolutionize the treatment of sinus conditions through the development of minimally invasive surgical devices.

2. Acclarent’s most successful products, and the company’s primary revenue generator, involved balloon sinuplasty (“BSP”). Balloon sinuplasty is a type of nasal endoscopic surgery that uses small inflatable balloon catheters to drain nasal sinuses. It was a revolutionary development because it provided otolaryngologists with a viable alternative to a more destructive form of sinus surgery known as FESS, which is often associated with significant complications. Unlike FESS, BSP is a minimally invasive office procedure that eliminates the need for general anesthesia and the removal of healthy sinus tissue. It has been adopted by thousands of ENT physicians, become the standard of care, and been successfully performed on hundreds of thousands of patients to their considerable benefit.

3. None of the government’s charges related to Acclarent’s BSP products. Rather, the government targeted a separate device that Acclarent manufactured: the Relieva Stratus Microflow Spacer (the “Stratus”). During the years when it was sold, the Stratus generated only a small percentage of Acclarent’s revenues and had no material impact on the company’s valuation. Despite those facts, the government brought the full weight of its investigative and

prosecutorial resources to bear on Acclarent and on everyone at the company who was involved in the development, launch, marketing or sale of the device.

4. The Stratus was designed to be threaded into a patient's sinus. Upon insertion, the device was capable of serving two functions: (a) it could act as a mechanical spacer, to prevent scarring and adhesion of sinus tissue; and (b) it could elute fluid from a permeable membrane reservoir located at the tip of the device. Contrary to the government's allegations, patent filings for the device dating back to 2004 demonstrate that the Stratus, as designed, served a mechanical spacing function. Similarly, Acclarent's submissions to the FDA depicted both the mechanical spacer portion of the Stratus and the fluid-eluting perforated membrane reservoir at the end of the device.

5. Acclarent sought clearance from the FDA for the Stratus under a process known as 510(k). Section 510(k) permits the FDA to grant clearance to devices it deems substantially equivalent to devices it previously approved (so-called "predicate devices").

6. Acclarent pursued an incremental "stepping stone" approach to seeking 510(k) clearance for the Stratus. Such an incremental approach, which is legally permitted and commonplace, seeks initial clearance from the FDA for a single use defined by the manufacturer. After receipt of that initial clearance, the manufacturer may then seek subsequent clearances for additional uses. No requirement exists that a manufacturer identify in its initial 510(k) submission all uses for which it contemplates seeking future clearances. Nor does the FDA attempt to identify such additional uses. Rather, the FDA considers only the use specified in the submission pending before it.

7. Once a device is cleared for a particular use, the Food, Drug and Cosmetic Act ("FDCA") permits physicians to use that device "off label" for a different use without further



FDA clearance or approval. The FDA allows companies to distribute devices with knowledge that physicians intend to use them off label. Such knowledge, without more, does not establish a new “intended use” on the part of the manufacturer. The FDA also permits manufacturers to discuss off-label uses in response to requests or questions by physicians.

8. The FDA cleared the Stratus for use as a sinus spacer substantially equivalent to a predicate mechanical spacer known as the Rains Stent. At no point in the review process did the FDA indicate that its determination whether the Stratus could function as a spacer – substantially equivalent to the Rains Stent – was dependent on the device’s elution of saline from its membrane reservoir. Had elution been material to the FDA’s 510(k) substantial equivalency determination, the agency could – and presumably would – have requested information from Acclarent concerning the device’s rate of saline elution. It did not. In fact, as plainly depicted in the patent filings for the Stratus and in the device drawings that Acclarent submitted to the FDA, the mechanism by which the Stratus, as a physical spacer, keeps open the sinus ostium and cavity is through its protruding shaft. Like the Rains Stent, which contains no fluid, that mechanism of operation is not dependent on saline, and is therefore unaffected by the Stratus’s saline elution rate.

9. In Acclarent’s communications with the FDA, which spanned years, the company explicitly informed the agency that it wished and intended to seek a future indication authorizing use of the Stratus to deliver drugs to the sinus, including the steroid Kenalog, through the device’s permeable membrane reservoir. Acclarent also disclosed, and the FDA was aware, that substantial numbers of doctors were electing to use the Stratus off-label, not with saline, but as a mechanism for delivering Kenalog to the targeted sinus. FDA staff personally witnessed physician demonstrations of the Stratus with Kenalog at one or more medical conventions or

meetings. Staff also communicated to Acclarent that regardless of whether or when the agency cleared the Stratus for use with Kenalog, Acclarent could ship the device pursuant to the indication it had received, and doctors could then use the Stratus however they wished, including off-label with Kenalog.

10. Consistent with the foregoing, the FDA took no action relative to Acclarent or the Stratus despite knowing that considerable numbers of physicians were using it off-label with steroids. The FDA did not seek to rescind the Stratus's initial 510(k) clearance; it did not order Acclarent to pull the device from the market; it issued no warning letters; and it sought no labeling changes (until considerably later). In fact, as noted at trial, the FDA approved *five additional* 510(k) clearances for the Stratus pursuant to Acclarent's iterative approach to incrementally expanding the device's cleared uses, including for use in other sinuses. Throughout this entire time period, doctors continued their off-label use of the Stratus with Kenalog, and did so with the FDA's full knowledge.

11. Since long before the Stratus, physicians have used steroids, including Kenalog, to treat sinusitis and other sinus conditions. Every single otolaryngologist the government called to testify at trial acknowledged that treating sinus conditions with steroids is common; that they themselves use steroids to treat their own patients, including through the topical application of Kenalog; and that although treatment with steroids is safe, effective, and often the standard of care, it is nonetheless "off-label."<sup>4</sup> In fact, at the time Stratus received its initial 510(k)

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<sup>4</sup> See, e.g., Dr. Michael Armstrong Test., 6/8/2016 Tr. at 180, 184-86, 188, 192; Dr. Cathy Chong Test., 6/15/2016 Tr. at 126, 155-60, 172; Dr. Peter Hwang Test., 6/27/2016 Tr. at 54-55, 83-84; Dr. Anjum Khan Test., 6/29/2016 Tr. at 123-24; Dr. Martin Citardi Test., 6/30/2016 Tr. at 211-12, 217, 219-20; see also DX0135-0005 ("nasal corticosteroids are a mainstay of medical treatment for chronic rhinosinusitis, with 94-99% of surveyed otolaryngologists believing they are part of maximal medical therapy" (citing Lund, VJ, *Maximal Medical Therapy for Chronic Rhinosinusitis*, Otolaryngol. Clin. N. Am. 2005; 38, 1301-1310 and Kaszuba, SM and Stewart, MG, *Medical Management and Diagnosis of Chronic*

clearance, the FDA had not approved or cleared a single steroid or steroid delivery device for use in the sinuses, despite the widely recognized benefits of steroids in treating sinus conditions. Those benefits include the reduction of inflammation, the treatment of polyps, a lessened risk of adhesions, and the facilitation of drainage.

12. From the perspective of physicians, one of the benefits of the Stratus was that it could be used to topically deliver a precise quantity of steroids directly to a targeted sinus. In so doing, the device:

- a. Eliminated the need for patients to take systemic steroids, thus avoiding the risks posed by long term use of such medications;
- b. Ensured that steroids were applied directly where wanted and needed, unlike other topical forms of administration (like nasal sprays), where the steroids often do not make it all the way to the sinuses;
- c. Permitted the injection of a precise and limited quantity of Kenalog, and the extended release of that steroid, unlike physician-improvised techniques, which entailed squirting much larger quantities of steroids onto disposable gauze or into cut-off surgical glove tips, and then physically packing those objects into the sinus; and
- d. Spared patients from painful and invasive surgery to remove tissue and sometimes bone (FESS) and the complications and adverse effects that could arise from such procedures.

13. Doctors who used the Stratus with Kenalog were aware that they were using the device in an off-label manner. Acclarent and its sales representatives never misled any doctor about the fact that injecting the Stratus with Kenalog represented an off-label use. As observed by one letter writer with decades of industry experience: “Acclarent went well beyond what I have ever witnessed to make it clear to doctors what product indications had been approved.” *Letter from Bob Croce (former Johnson & Johnson Global Chairman and Acclarent board member),*

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*Rhinosinusitis: A Survey of Treatment Patterns by United States Otolaryngologists*, Am. J. Rhinol. 2006; 20:2006, 186-190).

Exhibit C-9. (All exhibits are attached to the accompanying Declaration of Michael J. Pineault.)

14. More than 30,000 Stratus devices were sold. Many were re-orders to doctors who found the Stratus to be a safe and effective treatment for their patients. Statistically, the device had an extremely low rate of adverse effects. It also involved the use of a far smaller quantity of Kenalog than other topical application techniques ENTs used prior to the Stratus's development. The FDA itself concluded that no safety limitation for the device's 510(k) clearance was warranted because there was no basis for concluding that the extensive off-label use of the Stratus with steroids was causing harm.

15. Acclarent sales representatives marketed and sold the Stratus using materials and procedures that were reviewed and approved in advance by employees in the company's Regulatory department. As this Court is aware, including from the hours counsel and the Court spent grappling with the jury instructions, the federal regulations governing the marketing and sale of medical devices are complicated and confusing, particularly where, as here, considerable numbers of physicians elect to use a device off-label.

16. To the best of their abilities, everyone at Acclarent, including Mr. Facteau, strove in good faith to ensure that the company complied with those regulations. On cross-examination, employee after employee – called by the government as part of its case in chief – stated that they had not believed they or the company was doing anything wrong. *See, e.g.*, Mollie Vanderkarr Test., 6/13/2016 Tr. at 242 (agreeing that “there was never one second in time when [she was] working with the Stratus . . . that [she] felt that [she was] engaged in any kind of wrongdoing”); Wendy Oakes Test., 6/15/2016 Tr. at 113-14 (never believed that anyone was breaking the law or doing anything to deceive the government); Kevin Convery Test., 6/16/2016 Tr. at 164 (agreeing that he “never, for one minute in [his] time with Acclarent, considered anything that [he] [was]

doing with Acclarent to be illegal.”); Fred Barrigar Test., 6/23/16 Tr. at 178 (agreeing he never thought that he was doing anything illegal at Acclarent); *id.*, 6/24/16 Tr. at 146 (testifying that as Project Manager he did not “think [he was] doing anything wrong when . . . working on Project Condor” and did not think they were breaking the law); *see also* GX2415 (approval of sales plan by Acclarent’s Regulatory Department); GX1153 (approval of Physician Discussion Guide by Regulatory Department). Rather, Acclarent and its personnel, including Mr. Facteau, followed the law as they understood it at the time.

17. The Government nonetheless argued to the jury, from the beginning of the six-week trial to the end, that Mr. Facteau had knowingly and intentionally engaged – and conspired to engage – in acts of fraud and deception, including but not limited to the making of false and misleading statements to the FDA, physicians, and others regarding the Stratus; had devised a fraudulent scheme to deprive others of money and property; and had caused the introduction of adulterated and misbranded devices into interstate commerce with the intent to defraud or mislead.

#### **IV. The Jury’s Verdict**

After a 30-day trial, the jury returned its verdict, rejecting the fraud theory that lay at the heart of the government’s case, and acquitting Mr. Facteau (and Mr. Fabian) on all charges alleging fraud, falsity, deception, misrepresentation, or misleading behavior. The sole counts of conviction were for misdemeanor violations of the Food, Drug and Cosmetic Act. As noted at page 1, above, these misdemeanor counts – unlike the felony counts on which the jury acquitted Messrs. Facteau and Fabian – required no finding by the jury that Mr. Facteau knowingly or actively engaged in any wrongdoing. The jury needed only to determine that Mr. Facteau had held a position of responsibility within Acclarent with the authority to prevent or correct the charged adulteration and misbranding violations, and that the violations nonetheless occurred and were not corrected.

It is on these strict liability “no intent” misdemeanor counts – and only these counts – that Mr. Facteau now comes before the Court for sentencing.

## **DISCUSSION**

### **I. Sentencing Framework**

Following *United States v. Booker*, 543 U.S. 220 (2005), the federal Sentencing Guidelines are advisory. Courts accordingly take a two-step approach to sentencing: (1) calculate the guidelines sentence and whether departures are warranted under the guidelines; and (2) determine whether a non-guidelines sentence is warranted by the factors set forth in 18 U.S.C. § 3553(a). *See United States v. Jimenez-Beltre*, 440 F.3d 514, 516, 518-19 (1st Cir. 2006) (*en banc*). The ultimate objective is to make an individualized, case-specific assessment and arrive at a sentence that is “sufficient, but not greater than necessary” to achieve the purposes of sentencing. 18 U.S.C. § 3553(a); *see also Booker*, 543 U.S. at 259-60; *Rita v. United States*, 551 U.S. 338 (2007); *Gall v. United States*, 552 U.S. 38 (2007); *Pepper v. United States*, 562 U.S. 476 (2011).

In fashioning such a sentence, the Court must consider, among other things, the history and characteristics of the defendant, the nature and circumstances of the offense, and the need for the sentence imposed. 18 U.S.C. § 3553(a). Even factors previously discouraged or forbidden under the mandatory Guidelines regime are now appropriate for consideration. *United States v. Smith*, 445 F.3d 1, 5 (1st Cir. 2006). Thus, a court may consider, for example, the defendant’s employment record, education and skills, family ties and responsibilities, role in the offense, civic or charitable service, and prior good works. *See id.*; U.S.S.G. Ch. 5 Part H.

Consistent with one of the purposes of the Guidelines, courts also should consider the “general appropriateness of imposing a sentence other than imprisonment in cases in which the defendant is a first offender who has not been convicted of a crime of violence or an otherwise

serious offense.” 18 U.S.C. § 994(j). Among other reasons, this nation needs “to deal with – and not just talk about – [its] over-incarceration problem.” *United States v. Dokmeci*, 2016 WL 915185, at \*1 (E.D.N.Y. Mar. 9, 2016) (Gleeson, J.). In doing so, courts “need to make smart, bold choices about two things: (1) the lengths of the prison terms [they] impose on those who need to be imprisoned; and (2) the categories of defendants they routinely incarcerate who don’t need to be imprisoned in the first place.” *Id.*

## **II. Guidelines Computation**

The government, Mr. Facteau and Probation agree that U.S.S.G. § 2N2.1 is the applicable Guidelines provision for the offense of conviction, 21 U.S.C. § 331(a), and that it specifies a Base Offense Level of 6. That, in turn, equates to a Zone A Misdemeanor, with an advisory Guidelines Sentencing Range (“GSR”) of 0-6 months.

The government seeks to double Mr. Facteau’s offense level by advocating for two upward role adjustments: (1) a 4-level organizer/leader increase under U.S.S.G. § 3B1.1(a); and (2) a 2-level increase for abuse of position of trust under U.S.S.G. § 3B1.3. The government bears the burden of proving that each of these role adjustments is proper. *United States v. Al-Rikabi*, 606 F.3d 11, 14 (1st Cir. 2010). It has failed to do so.

### **A. Section 3B1.1 Does Not Apply to Strict Liability Misdemeanors Due, Inter Alia, to the Absence of Participants with Criminally Culpable Mens Rea**

The government cites to no decision in this District that has applied an organizer/leader role adjustment in a strict liability misdemeanor case, for good reason. Section 3B1.1 applies only if a defendant oversaw other persons “who [are] *criminally responsible* for the commission of the offense.” U.S.S.G. § 3B1.1 nn.1-2 (emphasis added). Criminal responsibility requires “culpable participation”; in the absence of culpable participation, section 3B1.1 does not apply. *United States v. Tai*, 750 F.3d 309, 319 (3d Cir. 2014) (holding that applying section 3B1.1 in

“the absence of such a finding of criminal culpability of a participant constitutes plain error”); *United States v. Richardson*, 221 F. App’x 782, 785 (10th Cir. 2007) (“Because mens rea is an essential element of criminal culpability, an individual must have the requisite mens rea for the commission of a crime in order to qualify as a participant under the Sentencing Guidelines.”); *United States v. Holden*, 908 F.3d 395, 402 n.9 (9th Cir. 2018) (“[U]nknowing facilitators of an offense, even if they are ‘participants’ in the usual sense of the word, do not count.”).<sup>5</sup>

The jury’s verdict found no criminal intent on the part of Mr. Facteau or anyone else. Further, the jury specifically found Mr. Facteau not guilty of Count 1’s conspiracy charge, thereby rejecting the government’s sweeping assertion that Mr. Facteau and more than 80 other Acclarent employees participated in a conspiracy to introduce adulterated or misbranded devices into interstate commerce. Because, as a result, no Acclarent employee qualifies as a culpable criminal participant under section 3B1.1, that role adjustment cannot and does not apply.

It is no response for the government to contend that Mr. Facteau’s misdemeanor convictions did not require the jury to find that he, personally, acted with criminal intent. The application of section 3B1.1 does not turn on whether Mr. Facteau, as a responsible corporate official, could be found strictly liable for misdemeanor violations in the absence of intent. Rather, it turns on whether the government can satisfy section 3B1.1’s requirement that it prove Mr. Facteau organized or led other criminal participants, or a criminal organization whose

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<sup>5</sup> See also *United States v. Vega*, 826 F.3d 514, 539 (D.C. Cir. 2016) (“An individual is ‘criminally responsible’ under §3B1.1 only if ‘he commit[s] all of the elements of a statutory crime *with the requisite mens rea*.’”) (emphasis in original) (quoting *United States v. McCoy*, 242 F.3d 399, 410 (D.C. Cir. 2001)); *United States v. Bisong*, 645 F.3d 384, 398 (D.C. Cir. 2011) (“supervision of an unwitting individual cannot justify an enhancement,” and “where the participant has knowledge but commits no actus reus justifying criminal responsibility the supervision of such person similarly may not justify an enhancement”); *United States v. Maloof*, 205 F.3d 819, 830 (5th Cir. 2000); *United States v. Markovic*, 911 F.2d 613, 616 (11th Cir. 1990).



criminal activity was “otherwise extensive,” absent proof of mens rea on the part of *anyone*. It cannot.<sup>6</sup>

In that regard, a comprehensive search for District of Massachusetts sentencings of strict liability FDCA misdemeanors found none in which the court applied a role adjustment under section 3B1.1. A chart summarizing the salient facts regarding these cases is attached at Exhibit A-1. A companion chart of strict liability FDCA misdemeanor sentencings by other district courts within the First Circuit (attached at Exhibit A-2) similarly shows that no other courts in the First Circuit appear to have applied a role adjustment in such cases under Section 3B1.1.<sup>7</sup>

The sentencing in *United States v. Holloway* is particularly instructive. In *Holloway*, the government charged a regional sales executive who supervised approximately 100 employees at a pharmaceutical company with having “directed” and “required” her employees to promote Bextra off label despite being “on notice” that certain off-label documents “should not be used.” Sent’g Tr. at 9-10, *United States v. Holloway*, No. 09-cr-10089 (jgd) (D. Mass. June 18, 2009) (attached at Exhibit B). Despite making those allegations, the government—represented by one of the two AUSAs involved in this case—confirmed in court that it did not object to adhering to the Guidelines calculations set forth in the plea agreement (which computed an offense level of 4). Notably, the government did not respond to, or otherwise take issue with, defense counsel’s

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<sup>6</sup> See, e.g., *United States v. Lucena-Rivera*, 750 F.3d 43, 50 (1st Cir. 2014) (requiring that defendant have controlled, organized or managed “criminal actors” not simply criminal “activities”); *United States v. Thung Van Huynh*, 884 F.3d 160, 171 (3d Cir. 2018) (noting the need to determine, *inter alia*, whether the activities at issue were undertaken with “specific criminal intent”).

<sup>7</sup> The cases listed in Exhibit A-1 were identified by running a Westlaw Edge search for any District of Massachusetts case, pleading, or brief that referenced “333(a)(1)” and listing the cases in which there were no accompanying felony convictions. A research analyst then performed an Internet search for any other cases involving only misdemeanor-level offenses and supplemented the list. While counsel cannot be certain that Exhibit A contains every misdemeanor 21 U.S.C. § 333(a)(1) conviction in this District, it includes every such case found pursuant to the foregoing search, regardless of outcome. Exhibit A-2 was prepared by performing similar research in the other Districts comprising the First Circuit.

argument at sentencing that because the case involved a strict-liability offense and the defendant had no criminal intent, “the whole concept of supervising or managing criminal activity” did not apply. *Id.* at 4.<sup>8</sup>

Just as section 3B1.1 was not applied in *Holloway* – or in any other strict-liability FDCA case that counsel has been able to locate in the District of Massachusetts or any other district court in this Circuit – it does not apply here.

**B. Section 3B1.3 Does Not Apply Because It Requires “Abuse” of a Position of Trust**

The government’s request for a 2-level upward adjustment for abuse of a position of trust under section 3B1.3 is equally misplaced. The government argues that because Mr. Facteau, as Acclarent’s CEO, had final authority over the decision to launch and begin distribution of the Stratus, he occupied and “use[d] a position of trust for the purposes of USSG § 3B1.3.”

Contrary to the government’s assertion, however, section 3B1.3 does not apply simply because Mr. Facteau held a high-level corporate position. Rather, it requires that a defendant have occupied a position of trust and that the defendant have *abused* that trusted position by using it to facilitate or conceal the offense. *See, e.g., United States v. Parilla Roman*, 485 F.3d 185, 192 (1st Cir. 2007); *United States v. Reccko*, 151 F.3d 29, 31 (1st Cir. 1998). The government must establish both elements. It has failed to do so here.

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<sup>8</sup> That *Holloway* involved a plea is of no moment. Department of Justice policy, and the Guidelines, required the government to accurately calculate and inform the court of the defendant’s offense level. *See* Justice Manual § 9-27.400 (“Department policy requires transparency and honesty in sentencing; federal prosecutors are expected to identify for the court departures when they agree to support them. For example, it would be improper for a prosecutor to agree that a departure is in order, but to conceal the agreement in a charge bargain that is presented to a court as a *fait accompli* so that there is neither a record of nor judicial review of the departure.”); U.S.S.G. § 6B1.4 cmt. (“[I]t is not appropriate for the parties to stipulate to misleading or non-existent facts, even when both parties are willing to assume the existence of such ‘facts’ for purposes of the litigation. Rather, the parties should fully disclose the actual facts and then explain to the court the reasons why the disposition of the case should differ from that which such facts ordinarily would require under the guidelines.”).

Instead, the government impermissibly treats Mr. Facteau's occupancy of an executive position as synonymous with the abuse of a position of trust. It is not. To accept the government's argument would transform § 3B1.3 from a fact-specific enhancement reserved for individuals who "*abused* a position of public or private trust" into a generic one-size-fits-all increase that would apply to virtually every single executive defendant. Such an interpretation runs squarely counter to the Guidelines' core objective, which is to determine sentences based on individualized factual assessments.<sup>9</sup>

It is therefore not enough for the government to argue that Mr. Facteau possessed and exercised the type of authority held by virtually every single chief executive officer. Rather, the government bears the burden of establishing not only that Mr. Facteau occupied a position of trust but also that he did something that rose to the level of an *abuse* of that position. In a case where the jury did not even find that Mr. Facteau engaged in intentional criminal conduct, the government falls well short of meeting its burden.

The government's reliance on *United States v. Gonzalez-Alvarez*, 277 F.3d 73, 81-82 (1st Cir. 2002), to contend otherwise rests on a fundamental misperception. Unlike this case, *Gonzalez-Alvarez* did not involve strict liability misdemeanors. It was a felony sentencing involving a defendant convicted of having intentionally and fraudulently deceived consumers into "reasonably believ[ing] they were purchasing milk compliant with all government health regulations [including onerous tests for safety], but [who] in fact received a different product of unknown safety" and were "robbed of the benefit of their bargain. . .and suffered an actual loss."

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<sup>9</sup> It also would subject Mr. Facteau (and other corporate executives) to impermissible double punishment on account of their management positions: first, by rendering them strictly liable on RCO grounds; and second, by increasing their Guidelines level pursuant to an organizer/leader enhancement.

277 F.3d at 80. The case is wholly inapposite to this one – in which the jury acquitted Mr. Facteau on all charges of fraud and deception.<sup>10</sup>

In sum, it is difficult to conceive of any executive convicted of strict liability misdemeanors who would not be subject to an enhanced Guidelines range under the government’s logic. Pursuant to the government’s reasoning, all executives invariably would receive a 4-level increase for being a “leader” and then a further 2-level increase for occupying and “using” a position of corporate trust. Because enhancements and upward adjustments under the Guidelines are intended to result from case-specific assessments that an individual defendant engaged in additional conduct deserving of additional punishment, the government’s rote application of a standard that, as in Mr. Facteau’s case, would automatically double the offense level of every executive convicted of strict liability misdemeanors is unsupported and should be rejected.<sup>11</sup>

Applied consistent with their letter and their spirit, the Guidelines yield a total offense level of 6, which translates to an advisory Guidelines Sentencing Range of 0-6 months (Zone A). Within Zone A, the Guidelines do not provide for a sentence of imprisonment, unless the Chapter Two provision applicable to the offense of conviction expressly requires such a term, which it does not. U.S.S.G. § 5C1.1(b).

### **III. Application of 18 U.S.C. § 3553(a)**

Application of the factors set forth in 18 U.S.C. § 3553(a) furnishes additional support for a non-incarcerative sentence. Those factors include Mr. Facteau’s personal history,

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<sup>10</sup> The same is true for the other cases cited by the government in its PSR Objections.

<sup>11</sup> Patrick Fabian, in his Sentencing Memorandum, opposes the government’s request for identical role adjustments in computing his advisory guidelines sentencing range. *See* Defendant Patrick W. Fabian’s Sentencing Memorandum at Parts IV and V. To avoid duplication, Mr. Facteau incorporates by reference the additional legal arguments advanced by Mr. Fabian in opposition to the government’s requested adjustments.

characteristics and circumstances, as detailed in the dozens of letters submitted in connection with his sentencing hearing. They also include the nature and circumstances of the offense, which, as the jury determined, involved no fraud, falsity, deception, or misrepresentation. Finally, the factors include the purpose and need of the sentence imposed, which, when considered in the full context of this case, and the fact that Mr. Facteau already has served the equivalent of nearly 6 years of probation and/or supervised release, warrants a determination that no more is needed to accomplish the purposes of sentencing.

**A. Mr. Facteau's Personal History, Characteristics and Circumstances**

Mr. Facteau just turned 51 years old. Raised in modest circumstances in Florida by his father, a public high school football coach, Mr. Facteau attended a state university and then made his own way in the world, through hard work, a commitment to excellence, and a deep passion for the work of medical device manufacturers and the benefits their products provide to patients. Mr. Facteau presently serves as the chief executive officer of just such a company, Earlens, leading its approximately 200 employees in their efforts to develop a revolutionary new hearing aid.

For all his professional accomplishments, Mr. Facteau is first and foremost a caring and empathetic person. The father of seven children, including two stepchildren, Mr. Facteau is known not just for his business skills, but also for his integrity, self-sacrifice, and genuine commitment to others. The stories and sentiments expressed in the many letters submitted to this Court speak to these pillars of Mr. Facteau's life: his hard work; his devotion to family, friends and colleagues; his role as a trusted and gifted business leader dedicated to helping patients; and his unfaltering honesty and high ethical standards.

### 1. A Hard-Working and Fair Man

As described by his family, Mr. Facteau was raised in a family committed to honesty, responsibility and hard work. “[F]rom the time he was able to understand, [Bill] was taught the importance of honesty and responsibility and to fight for what is right.” *Letter from Michael and Jennifer Facteau (father, stepmother)*, Exhibit C-19. Even as a child, Mr. Facteau was driven and that drive to succeed led to academic excellence and leadership positions on sports teams. As he grew into an adult member of the workforce, his colleagues, friends, and family observed that Mr. Facteau “always had the drive to perform his best no matter the circumstances, and would never give up.” *Id.*

Mr. Facteau’s childhood work ethic helped him grow into an employee, manager, and leader who works extremely hard and demonstrates a commitment to fairness, open-mindedness and excellence in everything he does. He entered the industry as a wound technician and clinical sales representative. Those who have supervised Mr. Facteau describe him as “always an overachiever” and “smart, driven, hardworking, motivational, transparent and highly ethical.” *Letter from Henry Plain (past supervisor, board member)*, Exhibit C-35. Those who trained under Mr. Facteau over two decades ago describe Mr. Facteau’s “commitment to excellence, professionalism, and work ethic,” even then. *Letter from Ed Marti (former colleague)*, Exhibit C-31 (noting that as a result of his ethics, dedication to surgeons’ needs, and success, Bill rose through the ranks during the 1990s).<sup>12</sup> As observed by Nicholas Sherman, a Professional Education Manager who has worked with Mr. Facteau for almost a quarter of a century at five

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<sup>12</sup> *Accord Letter from Dr. Peter Catalano (Acclarent SAB)*, Exhibit C-2 (“Bill was savvy, smart, well informed, fair in judgment, open to new ideas, and extremely hard working.”); *Letter from Roseanne Davies (mother)*, Exhibit C-10; *Letter from Drew Dundas (colleague, Earlens)*, Exhibit C-13; *Letter from James Farrey (friend)*, Exhibit C-21; *Letter from William Thomas (friend)*, Exhibit C-44; *Letter from Bob Wood (colleague)*, Exhibit C-50.

different companies and was a customer of Mr. Facteau's before that: "Throughout my 24 years working under Bill's leadership I have never seen someone working so hard to help patients, employees, and their families." *Letter from Nicholas Sherman*, Exhibit C-40.

Mr. Facteau's colleagues and employees—both past and present—emphasize that while holding them to high standards, he also treats them with compassion, fairness, and empathy. Former Acclarent Vice President of Research & Development John Chang "observed how Bill consistently treated colleagues with respect and empathy both in public and private settings. . . both when talking with someone in person and when talking about that person when they weren't in the room." *Letter from John Chang*, Exhibit C-3. Former Acclarent Regulatory Affairs Manager Deb Cogan writes that Mr. Facteau "proved himself to be a caring leader" with "compassion and empathy" for his team members. *Letter from Deb Cogan*, Exhibit C-7. "He is genuinely kind and respectful, a truly decent man and a natural leader. . . . Should the occasion ever arise I would jump at the opportunity to work for him again." *Id.*; accord *Letter from Dr. Andre Cheng (colleague, Acclarent)*, Exhibit C-4 ("I count [Bill] as one of the most important positive influences on my life . . . [he] is one of the most genuinely thoughtful souls I know. . . . [Bill] taught me to prize honesty, transparency, loyalty, a sense of shared purpose. How you treat people, especially when no one is watching or when it's the secretary or most junior member of the team, was particularly important in his judgement of one's character."); *Letter from Nicholas Sherman*, Exhibit C-40 ("With employees, he listens to both sides and is fair with everyone. . ."). Mr. Facteau got where he is through hard work and drive but he balances that with notable compassion, fairness, and empathy.

## **2. A Caring Man Devoted to His Family, Friends, Colleagues and His Faith**

Despite the demands of his job, Mr. Facteau prioritizes his family. One theme of the letters submitted in support of Mr. Facteau is the number of colleagues who commend his

dedication to going the extra mile (sometimes literally) to be there for his family despite the demands inherent in running a start-up business. As educational non-profit CEO Andrew Cleeland—with whom Mr. Facteau co-chaired a series of educational events for the American Heart Association—describes Mr. Facteau: “He is a loving and devoted father . . . , a wonderful husband . . . , and a great friend and mentor to many.” *Letter from Andrew Cleeland*, Exhibit C-6; *see also Letter from William Thomas (friend)*, Exhibit C-44 (“Bill is a great husband and father, the best I’ve witnessed in my lifetime.”); *Letter from Alan Will (industry colleague and friend)*, Exhibit C-48 (“Bill is a proud father and dedicated husband. He compassionately cares for his children, providing a loving and principled example for them.”).<sup>13</sup>

Mr. Facteau has a large family, and not one member of that family escapes his attention or devotion. Several of the letters discuss steps that Mr. Facteau has taken to overcome what might otherwise be obstacles to family relationships. When three of his children moved to another part of the Bay Area (approximately 50 miles away) as a result of the divorce and ensuing custody dispute that followed the trial in this case, Mr. Facteau made sure he was able to play an active role in their lives in a way that would avoid any unnecessary disruption of their childhood. Faced with the prospect of shuttling his children back and forth between Danville and Atherton for their weekly transitions between parents, Mr. Facteau rented a second residence that ensures that during their time with him, his children can continue to see the same friends,

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<sup>13</sup> *See, e.g., Letter from Scott Durall (colleague)*, Exhibit C-14 (describing Mr. Facteau’s uncompromising commitment to family”); *Letter from Bob Croce (Acclarent board member)*, Exhibit C-9 (“Bill is a family-oriented individual. He is incredibly involved with his children. This ranges [from] church activities to sports.”); *Letter from John Chang*, Exhibit C-3 (“At times I would see how tiring it was for Bill to juggle the demands of running a start-up and being engaged in the lives of his sons. But it was evident how much he was dedicated to being there for his sons”); *Letter from Mark Bishop (colleague)*, Exhibit C-1 (“[W]e have worked together closely for 14 years. I would describe Bill as a dedicated family man . . . .”); *see also Letter from Dr. Peter Catalano*, Exhibit C-2; *Letter from Greg Garfield (colleague)*, Exhibit C-23.



participate in the same afterschool activities, and live the same lives that they do the rest of the week. As a result, Mr. Facteau has spent the last three to four years living part-time in Atherton and part-time in Danville.<sup>14</sup>

Letters from Mr. Facteau's mother, children and wife describe his dedication to family and the important role he plays as husband and father:

*Letter from Roseanne Davies (mother):*

Bill has a strength of character that is what any mother would wish for in their child. He is a kind and considerate person who always puts others wants and needs before his own. He has five wonderful children exemplifying his commitment to his family in their actions – they are well rounded, personable and kind and also willing to help others, as they have seen their father's example of this their entire lives. . . .

When the children were younger, the first thing he did when he came home at night was take time to sit with them and ask about their day. He would be the one doing the bedtime routine of baths and story time and all the children looked forward to that alone time with him, just as he looked forward to time alone to devote to that particular child, showing them how important they were to him.

Exhibit C-10.

*Letter from Billy Facteau (son):*

As a father, Bill Facteau is caring, passionate and filled with joy. He is always willing to go the extra mile to make sure that his friends and family are on the right track.

Exhibit C-16.

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<sup>14</sup> See *Letter from Stephanie James (friend)*, Exhibit C-25; *Letter from Henry Plain*, Exhibit C-35; *Letter from James Farrey*, Exhibit C-21. Another example of Bill's efforts to build active family relationships are the way in which Mr. Facteau has made sure that a two-decade difference in age does not prevent him and his siblings from supporting and loving each other. See, e.g., *Letter from Ryan Facteau (brother)*, Exhibit C-20 ("His family always come first and believe me he has a large family. . . . Being the oldest, I believe he feels the responsibility to watch over his younger siblings." *Letter from Rebecca Wilson (sister)*, Exhibit C-49 (describing how "Billy would check in with me" regarding her post-college life and student loans and ultimately paid those loans off for her).

*Letter from Clayton Facteau (son):*

During this past year my dad and I have connected in ways that both of us thought unimaginable. . . . As a son who looks up to his dad because of his big accomplishments, it is easy to get lost on the path of trying to make him proud. But what I hadn't fully grasped, until this year, is that no matter what, whatever decision or way we go about our days, my dad will always be proud of us.

Exhibit C-17.

*Letter from Lara Facteau (wife):*

Bill is not only a loving and doting husband but an amazing father and stepfather to my two boys.

Exhibit C-18.

Mr. Facteau's devotion and commitment extends well beyond his family, to include friends, colleagues, the broader community, and his deep religious faith.

Numerous friends, colleagues, and family members note Mr. Facteau's commitment to charity.<sup>15</sup> Mr. Facteau has likewise supported the Menlo Park Church through gifts of both time and money.<sup>16</sup>

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<sup>15</sup> See, e.g., *Letter from Fritz and Camille Schuler (brother- and sister-in-law)*, Exhibit C-38 ("In addition to his fundamental desire to improve the quality of people's lives, whether at home or in the workplace, what we find most admirable about Bill is his staunch and steadfast dedication to the charities he supports. His generosity extends to a variety of organizations, including the American Heart Association, the Pacific Research Institute, and the Navy Seal Foundation. But close to his heart is the passion he shares for non-profits such as The Boys and Girls Club of the Peninsula and the 49ers Academy, charities with a mission to help impoverished and disadvantaged youth gain equal access to a quality education and the potential to live a fulfilling life."); *Letter from James Farrey*, Exhibit C-21 ("[Bill] has always shown a strong commitment and dedication to providing for his family, his employees and his friends. His generosity is unequalled, and I have never heard Bill say 'no' to anyone asking for his time or involvement."); see also *Letter from Dr. Ketan Muni (colleague)*, Exhibit C-33 (describing how, during COVID-19, Mr. Facteau has helped lead a project at Earlens designing and manufacturing masks and safety shields, which have been shipped to physicians and clinics around the country at cost).

<sup>16</sup> *Letter from Roseanne Davies*, Exhibit C-10 ("Bill has always given back to his community and his Church. He volunteers at fund raisers for various organizations and has served as Chair of Fundraising to his chapter of the Heart Association several times in past years. He is very involved with the Menlo Park Church, donating time and money to their various activities all through the year."); *Letter from Michael and Jennie Facteau*, Exhibit C-19 ("God has always played an essential role in our lives, and we raised our children to understand that ultimately He is the one in control. . . . Bill understands the importance of

As friend Stephanie James observed, Mr. Facteau's devotion and commitment continues well beyond those traditional examples of generosity:

Bill does not do what is easy; he does what is right. I have witnessed over the years his repeated prioritization of those he loves and to whom he has a responsibility, be it family, friends, employees, colleagues, investors, and those less fortunate. Indeed, I struggle to think of a man who is more devoted and dedicated to the people who count on him.

*Letter from Stephanie James, Exhibit C-25.*

Long-time friend James Walker provides a particularly personal example of how Mr. Facteau prioritizes those he loves:

[REDACTED]

[REDACTED]

[REDACTED]

*Letter from James Walker, Exhibit C-45.*

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God as a part of his daily life, and that, combined with the work ethic and values that we instilled in him since he was young, has guided him to be an extraordinary, faith-based leader and father.”); *Letter from Tom Correia (friend)*, Exhibit C-8 (“Growing up in the heart of Silicon Valley, you learn to detect who has the ‘what’s in it for me and how can you help me?’ attitude. Bill never asked what you did for living, what type of car you drove, how big my house was or what city I lived in. With Bill, it’s always been about family, friends and fulfillment.”)

**3. A Trusted and Respected Executive Dedicated to Patients, Physicians, and Employees**

Colleagues and customers alike are unanimous in describing Mr. Facteau as a man dedicated to helping physicians so that they can provide better care to their patients. Mr. Facteau chose to join the medical device industry to help patients, and colleagues from throughout his nearly three decades in the industry agree in their observation of that intent.

Mr. Facteau's desire to help patients was observed from the moment he joined the medical device industry. His first boss at U.S. Surgical praised Mr. Facteau for taking a "patient-centric approach to the busines[s]" that distinguished him from other representatives. *Letter from Scott Durall*, Exhibit C-14. Then a customer of Mr. Facteau's, Nicholas Sherman similarly noted that "even then Bill was working to do the right thing for the hospital in the care of patients. . . . What I saw then and still today see in Bill was someone who wanted to help physicians solve problems for patients, and work to improve skill levels for physicians as products and procedures advance." *Letter from Nicholas Sherman*, Exhibit C-40.

Since then, Mr. Facteau has become widely known for his deep commitment to the needs of the patients and doctors who use his companies' products. He has earned the respect of medical device industry colleagues for his dedication, his integrity, and his singularly gifted leadership skills at bringing to market innovative products that have revolutionized the standard of care provided to patients:

*Letter from Andrew Cleeland (non-profit CEO):*

Bill is highly respected in our field . . . . He is passionate about leadership and innovation in healthcare . . . . Bill has had a profound impact on his many employees, their families, and on patients via the technologies he has successfully brought to market. He is an exemplary professional, one who I seek guidance and counsel from regularly. . . . With strong conviction, I truly believe that Bill is a good, honest man - one that I would be proud for my son to one day emulate.

Exhibit C-6.

*Letter from Dr. Suzy Levy (colleague, Earlens):*

[He] has worked tirelessly over his career to bring novel products to market that benefit people's quality of life.

Exhibit C-27.

*Letter from Deb Cogan (Regulatory manager, Acclarent):*

Bill has a huge capacity for empathy and genuinely cares about people, especially patients in need. Following a request from doctors, it was Bill who persuaded his leadership team at Acclarent to pursue a clinical study and obtain FDA clearance for a pediatric labeling claim because, as he put it, *it was the right thing to do*. [(emphasis in original)] . . . From a business perspective, Acclarent had no interest in the pediatric market and the company never marketed to pediatrics; not a single brochure or marketing campaign was ever developed, I know because I was tasked with reviewing such materials. The cost of the study was exorbitant, it took more than two years to complete. My department submitted the 510(k) application, and we obtained a pediatric indication which is still in effect today. This was a truly altruistic pursuit and I believe is a typical example of how Bill thinks about healthcare—it's all about the patients. I was proud to be a member of his team.

Exhibit C-7.

*Letter from Greg Garfield (colleague):*

I have known Bill for almost 15 years as a colleague and a friend. Working side-by-side with Bill at Acclarent for 5 years provided me deep exposure and understanding of his commitment to making a difference in people's lives. . . .

As someone who worked together with Bill for many years, and has chosen to invest in Earlens under his leadership as CEO even after his conviction in this case, what I hope to convey to you is Bill's deep commitment to making a difference in patient's lives through his chosen field of healthcare. Bill has run organizations that have brought forward lifesaving and life altering technologies to the benefit of patients throughout the United States and all over the world. While Bill is aware of the importance of making these companies a commercial success, I have never seen him let that obstruct his vision for ensuring the products are safe and effective for patients. In fact, Bill's unwavering commitment to developing technologies that make a difference in patient's lives frequently makes companies he runs or is associated with successful because the products are so impactful. As those companies become successful under his leadership, they employ hundreds of individuals committed to making a

difference, and ultimately bring forward products that positively impact thousands of patients.

I would have understood if Bill chose to pursue a career in a field other than healthcare after his prosecution and conviction. However, he chose to continue because of commitment to making a difference in people's lives. . . . [H]is continued commitment to advancing the field of healthcare will benefit many more patients in the years ahead.

Exhibit C-23.

*Letter from Dr. Josh Makower (founder, Acclarent):*

Whenever faced with a question of how to proceed at Acclarent, his focus was always on doing what was best for patients, frequently checking in with our trusted scientific and clinical advisors.

Bill also had a special passion for advancing projects to improve the lives of children and parents, driving the innovation for specially sized sinuplasty tools for pediatrics, as well as the first technology ever to allow the placement of eartubes for small children without the need for general anesthesia.

Bill's commitment to the mission of serving patients was palpable in our regular meetings, and was inspiring to all of us who played roles with the company.

Exhibit C-29.

These are just a few of the dozens of letters extolling Mr. Facticeau's dedication and drive to identify what physicians need to treat their patients and bring that to physicians in order to improve patient care.<sup>17</sup>

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<sup>17</sup> *Accord Letter from John Chang*, Exhibit C-3 ("Bill would often remind and encourage the engineering teams to focus on the patient and physician needs whenever faced with difficult project decisions and tradeoffs."); *Letter from Dr. Ketan Muni*, Exhibit C-33 (when working with Bill, "it is always about the patient and [h]is safety first"); *Letter from Patrick Saxton (colleague)*, Exhibit C-37 (discussing efforts to serve patients and concluding "I am proud to work with Bill at Earlens because of this constant focus on improving patients' lives."); *Letter from Alan Will*, Exhibit C-48 ("Bill draws his motivation and inspiration from the patients he serves."); *Letter from Drew Dundas*, Exhibit C-13 ("Bill is a truly unique individual, blessed with the vision to set audacious goals, the intelligence to take on intense intellectual challenges, the tenacity to continue to struggle in the face of great adversity, the humility and courage to assume responsibility and the generosity to mentor others while achieving an immensely positive impact on the lives of his employees, community and family.").

#### **4. A Man of Unflinching Honesty and Unquestioned Ethics**

The letters submitted to this Court from Mr. Facteau's colleagues, friends, and family describe a man known and respected in his personal and professional lives for his integrity, unwavering honesty, and high ethical standards. They are unanimous in affirming that Mr. Facteau did his utmost to follow the rules because that is who he is – in every aspect of his life – whether he is selling his home to a stranger<sup>18</sup> or discharging his duties as CEO.

Former Johnson & Johnson Global Chairman Bob Croce comments:

I was a Board member for Acclarent and mentored Bill Facteau. My experience with Bill was that he was an outstanding executive and had high business ethics. I would not have worked with him if he did not have high ethical standards and integrity. One example of his ethics occurred when I attended a seminar that Acclarent held for physicians. The Stratus product was discussed by physicians from the podium. Before participants entered the presentation room, they were required to sign a statement that they understood that Stratus would be discussed and did not have approval for what some physicians might theorize. Inside the meeting this clarification was mentioned again before each speaker presented and it was also on the screen. . . . I thought Acclarent went well beyond what I have ever witnessed to make it clear to doctors what product indications had been approved.

*Letter from Bob Croce, Exhibit C-9.*

Numerous letter writers convey their opinion that Mr. Facteau led Acclarent with integrity. Dr. Peter Catalano of the Tufts University School of Medicine, who testified at trial, explains in his letter to the Court that “I am herein willing to stake my reputation on my belief that Bill Facteau is a good man, and honest man, a man who has improved the lives of countless

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<sup>18</sup> *Letter from Tom Correia, Exhibit C-8* (“Bill is trustworthy and forthcoming even when no one is looking. We had our first business transaction together in 2009, where I represented him in the sale of his home and the purchase of another. During the disclosure process, Bill made sure I knew everything about the history of the home, even the things know one [sic] would ever notice unless it was brought to their attention, such as previous floor conditions under carpets, problems that the previous owner might have had with neighbors, even down to the slight difference in a stair height. He wanted to make sure that whomever bought the house, knew exactly what they were buying with all of its attributes as well as imperfections.”).

patients, and a man whom I respect greatly as a friend, a leader, a father, a partner . . . . During his trial I testified on Bill's behalf because I knew . . . [b]oth Bill and Acclarent diligently strove to follow the law throughout my involvement with the company, and I hope my testimony made that clear." *Letter from Dr. Peter Catalano*, Exhibit C-2.

Similarly, Dr. Howard Levine describes how he joined Acclarent after seeing its sinuplasty products in action. Once there, Dr. Levine was consistently impressed by Mr. Facteau:

Bill insisted upon integrity in every task we performed. Bill required precision and excellence in our work. He cherished this because he knew it was the only way to create safe, effective and credible solutions to complex medical problems .

..

For me as a physician with interest in industry, if asked by Bill to serve with him or for him in any project where I could offer my service, I would immediately and enthusiastically accept. I would do this because I know that without question, there would be honor, scrupulousness and veracity in the work we would we do. Under Bill's leadership, I know I would be part of a team unified under his vision, driven by his passion and with a common and worthy goal to solve problems to make people better.

*Letter from Dr. Howard Levine*, Exhibit C-26.

As the following letters demonstrate, others who worked with Mr. Facteau at Acclarent agree:

*Letter from Karen Long (colleague, Acclarent):*

Bill Facteau, is a man of his word, of deep commitment to high morals and values").<sup>19</sup>

Exhibit C-28.

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<sup>19</sup> See also, e.g., *Letter from Nicholas Sherman*, Exhibit C-40; *Letter from Ketan Muni*, Exhibit C-33; *Letter from Sandy Wanner (colleague)*, Exhibit C-47; *Letter from Richard Walsh (former colleague)*, Exhibit C-46.



*Letter from Bob Wood (colleague, Acclarent):*

I have never known Bill to pursue a dishonest policy or act in a dishonest way whether working a sales territory or building a business. I am completely serious when I say this and know full well the context in which it will be read.

In the twenty-some years I have known him, he has always been scrupulously honest in an industry that rewards honesty. As his responsibilities increased with each promotion he set himself up as the example to follow in ethical behavior. He, and his team as an extension, was always there to participate in building a lasting enterprise rather than some fly by night shop. His track record at U.S. Surgical, Perclose, Abbott, Acclarent and Earlens all bear this out. . . .

I personally have never seen him use his authority to authorize cutting corners to achieve ends. Whether working for me, with me or I for him, we had innumerable discussions of people, policy, barriers, goals to be achieved and how to achieve them. Weighing all options, never in my experience did Bill stray from knowing and executing the right path whether it achieved the hoped for results or not.

Exhibit C-50.

*Letter from Dr. Josh Makower:*

Bill is a good person and I am deeply concerned about the impact this trial and his conviction has had upon him and his family over all these years. Bill consulted regulatory and legal experts in all his moves as he led the company. As a small company, we faced many challenges along the way - as do all small start-ups – but there never was a moment where I would have had reason to question Bill's integrity. Bill was transparent, embraced hard facts and worked hard to bring forward a therapy that truly had a chance to improve the quality of life for patients suffering from chronic sinusitis. Further, it was my understanding that over all those years, we as [a] company, and Bill in particular, maintained an open dialogue with FDA, and the company moved forward with all its steps in collaboration with, and in sync with, legal/regulatory guidance and clear precedents. Thus, the fact that he stands here convicted awaiting sentencing is something I find deeply sad and so unexpected given what I know of Bill and his character.

We shared a common mission, to help patients suffering from disease, and I believe that Bill did the best job he could to lead the company forward with personal integrity and with all of the appropriate regulatory and legal guidance.

Exhibit C-29.

*Letter from Henry Plain:*

As I testified [at trial] under oath, Bill Facteau is the best CEO with whom I have ever worked. He is smart, driven, hardworking, motivational, transparent and highly ethical.

Bill and the company's regulatory team kept the board updated on the discussion with FDA regarding the Stratus product. Based on my 40 years working in FDA regulated companies, I felt we were in full compliance and keeping FDA informed of our plans for the product with regulatory counsel review of our marketing plans/materials. It was very surprising that a product that was less than 1% of cumulative revenues would be the driving force behind prosecuting the CEO.

While every industry has some "bad actors" who cut corners or don't play by the FDA rules, Bill Facteau and Acclarent weren't in that category. In fact, Acclarent was and still is viewed by industry leaders as an example of true innovation and an extremely well-run company. And Bill continues to be viewed as one of the best CEOs in the business.

Exhibit C-35.

Other writers echo with their own attestations that Bill Facteau is a man of high integrity and ethical leadership. As Acclarent's former Vice President of Human Resources summarizes:

I have known Bill Facteau for eleven years; and reported to him in my role of Vice President of Human Resources at Acclarent. I have spent my entire career (almost 30 years) working in HR, mostly for medical device companies. I've worked for very large publicly traded companies and four Bay Area start-ups. I started my own business five years ago and have since consulted for nearly 20 companies. These combined experiences have exposed me to scores of senior executives, including Bill Facteau. I have seen exceptional leadership. I have seen horrific leadership. I can say with no hesitation that Bill Facteau is the most exceptional leader I've ever worked with.

Unlike other executives Bill encouraged me to take misconduct allegations seriously and do the right thing regardless of any potential impact on the company.

Seeing a man of such integrity go through the events of the past many years has been a gut-wrenching and frightening experience. I've often asked myself how is it possible that the most honest, genuine, and sincere boss I've ever known could find himself in this position?

I am often asked would I work with Bill again? The answer is this. It would be an honor to work with him again; it would be an honor to have him mentor my children.

*Letter from Anne-Marie Hodgkinson, Exhibit C-24.*

As trial witness Henry Plain observes, the choice made by both insiders and outsiders to stand by Mr. Facteau speaks volumes. “I can state categorically . . . that if we believed that Bill did anything illegal or immoral at Acclarent, we would all run away from him. There are plenty of other CEOs and companies to back. We continue to support Bill Facteau because we believe in his integrity and leadership.” *Letter from Henry Plain, Exhibit C-35; Letter from Greg Garfield, Exhibit C-23.*

Despite knowledge of this case, Earlens has supported Mr. Facteau in continuing as the company’s CEO because of his character and his integrity. As described by Dr. Drew Dundas of Earlens:

I joined Earlens with full knowledge of the charges that had been brought against Bill and have remained acutely aware of his situation throughout his trial and over the subsequent four years. I felt confident in joining the company and working alongside Bill because during the time that I had known him, I had seen only highly ethical behavior, a willingness to accept guidance and advice from experts, humility, and an abundance of caution in all business and personal matters. Since that time, my position and support has remained solidly in favor of Bill, and my opinions of him as a moral, upright, considerate individual have only grown stronger as we have worked more and more closely over the years.

*Letter from Dr. Drew Dundas, Exhibit C-13.*

Similarly, Dr. Suzy Levy of Earlens reflects on Bill as “a humble, gracious, and kind individual of high integrity.” *Letter from Dr. Suzy Levy, Exhibit C-27* (“I would choose to work with Bill over another leader every day of the week – I consider it a gift and an honor to be able to work closely with him and learn from him.”). This sentiment is echoed by long-time friend Robert Skinner, who opines that Mr. Facteau is “a person of unshakeable character who behaves

with genuine care and pure intentions in all of his endeavors, public and private.” *Letter from Robert Skinner*, Exhibit C-41.

The consistent theme throughout each of these letters – whether from industry leaders, Acclarent employees, Earlens employees, friends, or family – is that people who know Bill Facteau unreservedly affirm that he is a man who consistently strives to follow the rules and is characterized by high integrity and ethical leadership.

Lara Facteau, Mr. Facteau’s spouse, fervently agrees:

As Bill's wife, I have a unique perspective because I see Bill in all types of situations. On good days and bad days, with family, friends, co-workers, and strangers. I have read some of the letters that people have written on his behalf, people who have known him for decades and attest to his kindness, generosity, leadership, and selflessness. I, too, can validate those are all attributes of Bill. Many have pointed out how he is a loving husband and father. With the fiercest possible conviction, I can tell you that is the Bill Facteau I know and love and is a far cry from the evil, greedy, self-serving man that the government tried to portray him as [at trial].

*Letter from Lara Facteau*, Exhibit C-18.

##### **5. Someone with Many Contributions Still to Make**

For all he has done thus far in his life, Mr. Facteau has many more contributions to make, including at Earlens, whose award-winning innovation in hearing aid technology targets two prominent patient complaints – poor sound quality and inability to distinguish background noise. Mr. Facteau’s leadership skills have helped shepherd this device from the lab into patients’ ears, where it has become a difference-maker in the lives of people who have received it (including letter-writers Dr. Howard Levine and Robert Skinner).

Dr. Rodney Perkins, the founder of Earlens, explains that he asked Mr. Facteau to become CEO of the company precisely because of his “ability to organize, motivate and lead a team” and thereby “take a concept and turn it into a reality for patients.” Dr. Perkins underscores the contributions Mr. Facteau has made and hopefully will continue to make:

Bill has made a significant contribution to healthcare by motivating, mentoring and encouraging others to take a concept and create a product that can improve the quality of life. I am hopeful that he will be able to continue to do so.

*Letter from Rodney Perkins, M.D., Exhibit C-34.*

Dr. Perkins is not alone in expressing this sentiment. Other letter writers agree:

*Letter from Alan Will:*

Bill draws his motivation and inspiration from the patients he serves. His leadership matters. I ask that you consider this deeply when you are deliberating his upcoming sentencing. It would be a loss to many patients, his employees and the industry to lose his leadership at this time.

Exhibit C-48.

*Letter from Greg Garfield:*

Bill has run organizations that have brought forward lifesaving and life altering technologies to the benefit of patients throughout the United States and all over the world. . . . As those companies become successful under his leadership, they employ hundreds of individuals committed to making a difference, and ultimately bring forward products that positively impact thousands of patients.

[Bill's] continued commitment to advancing the field of healthcare will benefit many more patients in the years ahead.

Exhibit C-23.

*Letter from James Farrey:*

In closing Judge Burroughs, it is my hope that my experiences with Bill may help frame your image of Bill, his integrity, his willingness to help others and contribute, more than others, in our community. His contribution is far reaching but his absence would immediately affect his children's development and his vast team of employees that he leads day after day.

Exhibit C-21.

**B. Nature and Circumstances of the Offense**

The foregoing letters, without more, powerfully support a sentencing disposition that includes no term of imprisonment. The nature and circumstances of the strict liability

misdeemeanors on which the jury returned convictions furnish additional support for such an outcome.

Contrary to the government's proffered narrative, which continues to advance allegations of fraud and deception incompatible with the jury's verdict, Mr. Facteau has provided a detailed summary of the relevant facts at pages 5 – 11, above. Without repeating that summary, its key points include the following:

1. Acclarent was not some criminal organization scheming to deceive and mislead the FDA. It was a highly regarded company that pioneered the development of minimally invasive surgical devices – most notably, balloon sinuplasty products – that revolutionized the treatment of sinus disease.
2. With the Stratus, Acclarent pursued, in good faith, a legally permissible incremental approach for obtaining 510(k) clearance from the FDA.
3. The FDA was not misled or deceived concerning the fact that physicians were using the Stratus off-label with steroids. To the contrary, the FDA was fully aware of that fact, knew that ENTs had been using steroids off-label for years to treat sinus disease safely and effectively, and proceeded to issue five additional 510(k) clearances for the Stratus even as the off-label use of that device with Kenalog continued unabated.
4. Mr. Facteau, together with other Acclarent employees, sought and followed the advice of regulatory experts as they strove, in good faith, to navigate a complex regulatory setting that has been widely recognized, for more than a decade, to be in desperate need of clarification. Br. of *Amici Curiae* Members of the Medical Information Working Group Supp. Def'ts at 7-8 (Dkt. #491); Mot. of Medical Device Manufacturers Association to Join MIWG *Amicus Curiae* Br. at 2 (Dkt. #495). Clarification is particularly needed with respect to devices like the Stratus, which have been cleared by the FDA for one use but are utilized extensively by physicians for another.
5. The regulatory landscape has been further unsettled by recent First Amendment commercial speech decisions. The government has responded to these decisions by backing away from its longstanding reliance on “off-label promotion” as the conduct it targets, and shifting instead to a still-evolving “totality of the circumstances” construct.

In view of the foregoing, whatever missteps the government believes Acclarent committed should have been dealt with administratively. Instead, the Boston-USAO opted to pursue criminal fraud and conspiracy charges.

The jury's rejection of those charges ratified what defendants have said from the beginning – this case has never been about fraud or deception. At best, it has only ever involved a complicated regulatory dispute in an unsettled area of the law that the government has failed – for years – to clarify.

**C. A Just and Sufficient Sentence**

Based on all the facts and circumstances set forth above, a just and sufficient disposition under both the Guidelines and 18 U.S.C. § 3553(a) would be to sentence Mr. Facteau to “time served,” in recognition of the nearly 6 years he has been subject to supervision by the Probation Department and constrained by release conditions imposed by the court.

No period of imprisonment is necessary or warranted. As discussed at page 15, above, a comprehensive search for all D. Mass. sentencings for FDCA misdemeanors has identified only 8 such cases.<sup>20</sup> None has resulted in a sentence of imprisonment or a sentence of home confinement. *See* Exhibit A-1. Similarly, none of the 14 other sentencings by district courts in this Circuit for FDCA misdemeanors has resulted in a sentence of imprisonment or home confinement. *See* Exhibit A-2. Mr. Facteau should not receive such a sentence either.

Nor is any period of probation or continued supervised release needed to accomplish the purposes of sentencing. Mr. Facteau has been living under the constraint of release conditions for close to 6 years, including periodic reporting obligations, supervisory visits and check-ins, travel restrictions, and when travel has been permitted, the disruption and indignity of airport searches and temporary detentions when this case has caused Mr. Facteau to be flagged by TSA systems and personnel for additional screening/examination. As the Supreme Court has

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<sup>20</sup> The small number presumably reflects the infrequency with which the government charges defendants with only FDCA misdemeanors (not felonies), and the equal rarity, when the government charges both, of a jury acquitting on all felony counts.

recognized, the restrictive impact of such conditions on a person's liberty is real. *Gall*, 552 U.S. at 48-49.

Further, the length of the time period that Mr. Facteau has been under supervision exceeds the maximum probationary period and maximum supervised release period applicable to the misdemeanor violations for which Mr. Facteau was convicted. *See, e.g.*, 18 U.S.C. § 3583(b)(3) and U.S.S.G. § 5D1.2(a)(3) (supervised release of up to 1 year); 18 U.S.C. § 3561(c)(2) and U.S.S.G. § 5B1.2(a)(1) (probation of 1-5 years).

Finally, the real-world punitive impact this case already has had on Mr. Facteau is significant. As several letter writers have observed, the government's decision to pursue felony charges, its insistence on arresting Mr. Facteau at his home, its issuance of press releases broadly publicizing its accusations – even after the jury acquitted Mr. Facteau on all felony charges – and the extended time period during which Mr. Facteau (and his family) have had to live with the burden of this case has exacted a heavy toll. The damage to Mr. Facteau's reputation among those who do not know him is considerable, and likely irreparable. The impact on his family has been significant. The pressure and strain of living with this case and its attendant uncertainty for the past 6 years has been immense.

The following excerpts exemplify what people have witnessed:

*Letter from Clayton Facteau:*

When he went to trial in Boston in summer of 2016[,] I've never seen a man so hurt. . . .

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

This isn't a man who would do something to hurt anyone, this man, my dad, has gone through hell multiple times and back and still remains to put others before him.



Exhibit C-17.

*Letter from Bernard Shay (colleague):*

In making your decision on what sentence to impose I would ask that you consider how his conviction has impacted the last four years of his life and will impact his life going forward.

In today's world a conviction like his comes up in every aspect of life, from signing up as a coach for his children's sports teams, to making time to meet with his parole officer, to needing to request permission for travel to applying for licenses. We have seen investors walk away from funding our company based solely on Bill's convictions. For a very proud man who is dedicated to his family, his employees and his patients, this has been four years of agony and embarrassment. He has endured it with grace and humility, but it is very apparent to those of us who work with him that it has had a real impact on him, his family and our company.

In short, while he has not been formally sentenced, he has been punished and has bourn and will continue to bear a very difficult burden arising out of his conviction. I would, therefore, very respectfully request that you consider not only the nature of his conviction, but the impact of that conviction has had and will continue to have on his day to day life and on his family. Even if he is eventually exonerated, that conviction will continue to come up in every internet search, background check and will shadow everything he does for the rest of his life.

Exhibit C-39.

*Letter from Lara Facticeau:*

Another unique perspective I can provide you is how Bill's indictment and trial has affected our lives, both personally and professionally, even today.

You may not know the details about Bill's arrest, but it took place in his home in the presence of multiple FBI agents and U.S. Marshalls. The FBI agent handcuffed him and walked him to the front of his street while neighbors watched. This act of public humiliation was purposeful and intentional and will never be erased from the memory of those that saw it transpire.

While waiting for trial, Bill had to go through a background check to coach his youngest son, an activity he has done with all four of his boys. Bill disclosed to the city Little League program that he was awaiting trial for felony charges. It was determined by the Little League board that Bill could no longer coach, breaking his and his five-year-old son's heart.

When traveling with our family, Bill often is detained for questioning. He and I have missed connecting flights due to him being interrogated by Customs Officials . . .

Exhibit C-18.

*Letter from Dr. Josh Makower:*

The impact that this trial and conviction has had upon Bill, his family and our local community of innovators has already been significant.

Families have been broken under the stress, and many friendships were strained, while we all tried to abide by legal guidance to limit communications while the trial proceeded.

Throughout it all, like through so many of the challenges Bill faced while we worked together, he remained positive and focused on success, with faith in the system and a belief that the truth would win out.

Like many of the principles I observed about Bill over those years, whenever presented with a challenge, he focused on how he could bring a better self forward and how he could own the feedback and be better tomorrow.

If there are lessons to have been learned through this process, I am confident Bill has learned them; some very painfully and personally.

My heart has been broken by the entire situation and all of us who know and care for Bill are praying for him and his family.

Exhibit C-29.

*Letter from Henry Plain:*

Bill Facticeau and his family have already paid an enormous price for his misdemeanor convictions.

[F]or reasons I can't explain or understand, Bill was arrested at his home in the early hours of the morning with police sirens and flashing lights. The only possible purpose was to ensure he would be publicly shamed in front of his family and neighbors. The broader community was also exposed to the significant press coverage that was notified to attend the arrest.

The humiliation and fallout were immediate. Parents at his kid's school shunned Bill and his wife. Assuming Bill's guilt, they made it clear that their children wouldn't be allowed to play or interact with Bill's children. The resulting embarrassment was a major factor in Bill's wife divorcing him and moving his three young children 45 miles away.

Exhibit C-35.

As the foregoing makes clear, no more is needed to accomplish the purposes of sentencing with respect to the misdemeanor violations that are before the Court – not deterrence, not punishment, not retribution, not rehabilitation.

For the same reasons, Mr. Facteau respectfully requests that any fine not exceed the range set forth in the statute defining the penalty for the underlying misdemeanor offense, which is “not more than \$1,000” per count of conviction. 21 U.S.C. § 333(a)(1).

Respectfully submitted,

WILLIAM FACTEAU,

By his attorneys:

/s/ Michael J. Pineault

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Dated: January 6, 2021

**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-participants on January 6, 2021.

/s/ Michael J. Pineault

Michael J. Pineault